

Attorney Docket No.: KBI-0003  
Inventors: Ranganathan and Dickstein  
Serial No.: 09/557,011  
Filing Date: April 20, 2000  
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#### **REMARKS**

Claims 1-4 are pending in the instant application. Claims 1-4 have been rejected. Claim 1 has been amended. No new matter has been added. Reconsideration is respectfully requested in light of these amendments and the following remarks.

#### **I. Objection to Claims**

Claim 1 is objected to because it is suggested that the term "PH" should properly read "pH" to conform to standard scientific practice. In accordance with the Examiner's suggestion, the term "PH" has been deleted and claim 1 has been amended to recite the term as "pH" to conform with standard scientific practice. Support for this amendment is found throughout the specification and particularly at page 16, line 11.

Applicants respectfully request withdrawal of this objection and allowance of the pending claims.

#### **II. Rejection of Claims Under 35 U.S.C. §112**

The Examiner has acknowledged that the claims are free of the prior art recited against them. However, the Examiner has

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rejected claim 1-4 under 35 U.S.C. §112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor at the time the application was filed had possession of the claimed invention. The Examiner suggests that claim 1 recites ". . . wherein the enteric coating disintegrates and dissolves at or above a pH of 7.5 . . . said bacterial source being kept within the microencapsulated coating to prevent microbial infection of patients". The Examiner suggests that this language is considered to be new matter in that the description of this matter was not disclosed in the original Specification as filed. The Examiner suggests that the information was not described explicitly nor implicitly within the Disclosure and thus, the newly claimed information does not freely flow from the Specification. It is suggested that because claims 2-4 depend upon claim 1, they also contain new matter since all of the limitations to Claim 1 are present in claims 2-4. The Examiner has required Applicants to remove the new matter from the claims. Applicants respectfully disagree and request reconsideration.

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The specification as filed clearly describes the enteric coating on page 8, lines 20-28 where it is recited:

"Enteric coating of the composition is specifically designed to deliver the sorbents and bacterial source at the ileal and colonic regions of the bowel where maximal resorption of uremic solutes and other molecules are found to occur. This is preferably achieved via an enteric coating material which disintegrates and dissolves at a pH of 7.5 or higher."

Further as recited in the original specification as filed, the microencapsulated coating is described at page 9, line 13-25:

"Microencapsulation prevents the binding of macromolecules and other digestive materials which substantially reduce the efficacy of the sorbents to specifically adsorb the uremic solutes to the sorbents of the mixture. The microcapsules pass through the bowel, with the mixture of sorbents adsorbing multiple uremic solutes and the bacterial source metabolizing urea and ammonia and urea, and are then excreted intact from the bowel. Thus, in this embodiment, the patient is protected from the possibility of microbial infection by the bacterial source as the bacterial source is kept within the microcapsule. Accordingly, in a preferred embodiment, compositions of the present invention are both microencapsulated and enteric coated."

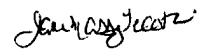
Thus, as clearly supported in the specification, the amendments to claim 1 are fully supported in the specification as filed. Applicants respectfully request withdrawal of this rejection and allowance of the pending claims.

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**III. Conclusion**

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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